

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IMMUNEX CORPORATION, et al., .  
Plaintiffs, .  
vs. . Case No. 16-cv-01118  
SANDOZ INC., et al., . Newark, New Jersey  
Defendants. . October 18, 2017  
.

TRANSCRIPT OF RECORDED OPINION  
BY THE HONORABLE MARK FALK  
UNITED STATES MAGISTRATE JUDGE

This oral opinion has been reviewed and revised in accordance with L. Civ. R. 52.1

This transcript has been **SEALED (AVAILABLE FOR PARTIES; NOT AVAILABLE FOR THE PUBLIC)** pursuant to Loc. Civ. R. 5.3(c) (2).

APPEARANCES:

For the Plaintiffs: No one was present

For the Defendants: No one was present

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1 (Commencement of proceedings)

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3 THE COURT: Okay. This is the case of Immunex

4 Corp. versus Sandoz. It is Docket 16-1118.

5 This is a patent infringement suit pursuant to the

6 Biologics Price Competition and Innovation Act, ("the

7 BPCIA"), relating to plaintiff's anti-inflammatory drug

8 etanercept, or "Enbrel." There are five asserted patents in

9 the case: the '182 Patent; the '522 Patent; the '225 Patent;

10 the '605 Patent; and the '631 Patent.

11 Procedurally, District Judge Cecchi held a Markman

12 proceeding on February 15, 2017. Discovery technically

13 closed on June 30, 2017. However, recent correspondence

14 indicates that discovery of some sort continued past that

15 date. It should also be mentioned that there is a pending

16 application to the Court to compel production of privileged

17 documents and for other relief, which would -- or could --

18 impact fact discovery.

19 Opening expert reports were served on August 28,

20 2017.

21 Responsive expert reports are due October 23, 2017.

22 Reply expert reports are due November 29, 2017.

23 And all expert discovery is to close January 19,

24 2018.

25 Dispositive motions are due January 30, 2018.

1           There are also pending various motions to seal  
2 discovery letters and a motion for summary judgment of  
3 infringement of Claim 1 of the '631 Patent. A trial date is  
4 set for April 17, 2018.

5           From the outset, it has been made clear by counsel  
6 that this case is on a tight schedule that the Court and  
7 counsel all intend to comply with.

8           The current dispute was raised by letters dated  
9 September 21 from the plaintiff; October 3 from the  
10 defendant; October 10 from the plaintiff; and October 16 from  
11 the defendant.

12           Plaintiff requests to strike "improper portions" of  
13 the report of one of defendant's experts, Dr. Carl Blobel.  
14 The "improper portions" are described as: (1) Newly  
15 disclosed references and theories of invalidity in connection  
16 with § 102(g); and (2) aspects of the report that rely on  
17 "improperly obtained evidence that is also inadmissible  
18 hearsay" (described as a declaration from a witness,  
19 Dr. Bruce Beutler, located in Texas).

20           Defendant opposes the application and contends that  
21 its references and theories of invalidity were already  
22 sufficiently disclosed; that, if necessary, it should be  
23 permitted to amend its invalidity contentions; and that the  
24 declaration from Dr. Beutler was obtained from a subpoena  
25 issued during fact discovery and with plaintiff's knowledge.

1                   First, I will address the newly disclosed  
2 references and theories of invalidity argument. Plaintiff's  
3 contention is that Dr. Blobel's report improperly advanced  
4 new theories and arguments of invalidity, pursuant to  
5 § 102(g), based on two allegedly newly designated pieces of  
6 prior art -- the "Smith '635 application" and "the Lauffer  
7 '703 application."

8                   Patent Rule 3.3(a) provides that invalidity  
9 contentions shall contain the following: "Prior art under 35  
10 U.S.C. § 102(g) shall be identified by providing the  
11 identities of the person or entities involved in and the  
12 circumstances surrounding the making of the invention before  
13 the patent applicant." L. Patent R. 3.3(a).

14                  Defendant claims that it has identified the persons  
15 involved and the circumstances of their research in  
16 compliance with Rule 3.3. It claims the Lauffer application  
17 was addressed in plaintiff's responsive contentions and  
18 therefore Immunex was clearly on notice of defendant's intent  
19 to rely on it. As for the Smith application, it issued at  
20 the Smith '760 Patent, which is expressly detailed in  
21 defendant's invalidity contentions.

22                  Plaintiff contends that defendant did not disclose  
23 either the Smith or the Lauffer applications in their  
24 invalidity contentions at all. It claims that defendant  
25 identified other applications and patents within the families

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1 involved, but that the patent rules require more; that is a  
2 showing where each item of prior art anticipates each  
3 asserted claim or renders it obvious (Rule 3.3(b)), and a  
4 chart identifying where "specifically in each alleged item of  
5 prior art, each limitation of each asserted claim is found."  
6 Rule 3.3(c).

7 "The local patent rules exist to further the goal  
8 of full, timely discovery and provide all parties with  
9 adequate notice and information with which to litigate their  
10 case." King Pharmaceuticals Inc. v. Sandoz, 2010 WL  
11 2015258 \* 4 (D.N.J. May 20, 2010). The patent rules "are  
12 designed to require the parties to crystallize their theories  
13 of the case early in the litigation and to adhere to those  
14 theories once they have been disclosed." Celgene Corp. v.  
15 Natco Pharma Ltd., 2015 WL 4138982 \*4 (D.N.J. July 9, 2015).

16 The Court concludes that defendant did not  
17 adequately disclose the '635 Smith application and the  
18 Lauffer '703 application within the contemplation of the  
19 patent rules. First, the two items are not expressly  
20 discussed in the invalidity contentions, nor do defendant's  
21 invalidity contentions expressly disclose that they believe  
22 either reference to constitute "constructive reduction to  
23 practice."

24 Second, referencing a patent family tree that  
25 includes within it a bunch of other applications and patents

1 (related or not) and claiming it is sufficient does not  
2 square with the letter of the patent rules; i.e., the  
3 disclosure of crystallized theories early in the case. Id.

4 Third, the Court rejects the notion that the patent  
5 rules only require "the identities of the persons or entities  
6 involved and the circumstances surrounding the making of the  
7 invention before the patent application" for prior art under  
8 § 102(g). This argument ignores the requirements of  
9 subsections (B) and (C) of Rule 3.3, which are express and  
10 require a relatively high level of specificity.

11 Having concluded the references and theories were  
12 not disclosed, the question becomes how to address the  
13 problem. The references could be stricken from the expert  
14 report, or the Court could permit defendant's alternative  
15 request to amend invalidity contentions to include them.

16 Local Patent Rule 3.7 governs requests to amend  
17 contentions. The rule allows for amendments "only by order  
18 of the Court upon a timely application and showing of good  
19 cause." Id. Good cause "considers first whether the moving  
20 party was diligent in amending its contentions." Id. If the  
21 moving party was diligent and good cause has been shown, the  
22 question becomes whether the "nonmoving party would suffer  
23 prejudice if the motion to amend were granted." AstraZeneca  
24 v. Dr. Reddy's, 2013 WL 1145359 \*3 (D.N.J. March 18, 2013).

25 Rule 3.7 provides a nonexhaustive list of examples

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1 that may support a finding of good cause: "(a) a claim  
2 construction by the Court different from that proposed by the  
3 party seeking amendment; (b) recent discovery of material  
4 prior art, despite earlier diligent searches; (c) recent  
5 discovery of nonpublic information about the accused  
6 instrumentality which was never discovered, despite diligent  
7 efforts, before the service of the infringement contentions;  
8 (d) disclosure of an infringement contention by a  
9 Hatch-Waxman party asserting infringement ... that requires  
10 response by the adverse party because it was not previously  
11 presented or reasonably anticipated...." Id.

12 Courts have also considered the following in  
13 determining whether good cause exists: reason for the delay;  
14 importance of the information to be excluded; the danger of  
15 unfair prejudice; the availability of a continuance; and the  
16 potential impact of a delay on judicial proceedings. See,  
17 e.g., International Development LLC v. Simon Nicholas  
18 Richmond and Adventive Ideas, LLC, 2010 WL 3946714 \*3 (D.N.  
19 J. October 4, 2010). In sum, amendment will be permitted  
20 where there is "a timely application, there is a showing of  
21 good cause, and the adverse party does not suffer undue  
22 prejudice." Celgene Corp., 2015 WL 4138982 \*4.

23 In considering whether an amendment should be  
24 permitted, a threshold issue is whether the amendment is  
25 timely. Plaintiff claims the amendment is not timely because

1 defendant has known about the omitted references since they  
2 served their invalidity contentions in the case. Defendant  
3 counters that the Lauffer application was not obtained until  
4 after its invalidity contentions were served and that the  
5 Smith application is referenced in the invalidity contentions  
6 in the sense that a patent that issued from the application  
7 is expressly relied on and disclosed.

8 The Court believes the application is sufficiently  
9 timely: One, defendant claims that it believed (and  
10 believes) that its contentions are sufficiently identified  
11 and there is no need for an amendment, a belief that it  
12 represents was in good faith. It could be found that these  
13 references were alluded to and that defendant was on notice.  
14 While not technically disclosed with specificity as required  
15 by the rules, they aren't a complete surprise, so it is not  
16 unreasonable to say that Plaintiff moved promptly upon it  
17 being raised, that their references were deficient. Two, the  
18 Lauffer application was obtained after invalidity contentions  
19 were served, so it could not be expressly included in  
20 invalidity contentions. Moreover, certainly, the Lauffer  
21 application was discussed in plaintiff's responsive  
22 contentions and the patent that was issued based on the Smith  
23 application was also discussed in both defendant's  
24 contentions and plaintiff's response. Courts have allowed  
25 amendments when they are based upon previously disclosed,

1      albeit not direct, references. See Kilopass Technology, Inc.  
2      v. Sidense Corp., 2012 WL 1901198 \*3 (N.D. Cal. May 24, 2012)  
3      (granting motion to amend when the amendment did not  
4      substantially depart from that what was disclosed  
5      originally).

6               The issue then becomes one of prejudice. However,  
7      the parties have not provided detailed information on this  
8      subject. The tension would seem to be the tight scheduling  
9      order in this case. Based on the information provided and  
10     the reasons given, the Court will conditionally permit the  
11     amendment of the contentions and allow plaintiff to advise  
12     the Court what steps and accommodations are needed to  
13     alleviate any prejudice. The Court will be extremely  
14     accommodative in permitting plaintiff what it seeks to  
15     alleviate prejudice. This could include further discovery,  
16     cost sharing, changing of the dates of expert submissions,  
17     etc.

18               The parties are directed to immediately meet and  
19     confer on this subject. If there is further information to  
20     be provided to the Court or if the parties cannot reach  
21     agreement, the parties should immediately contact the Court.

22               In making this decision, in addition to the local  
23     patent rules which have been cited, the Court notes that this  
24     can be analogized to the exclusion of evidence, which has  
25     been described as an "extreme" sanction, not normally imposed

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1 absent a showing of willful deception or flagrant disregard  
2 of a court order by the proponent of the evidence.  
3 Konstantopoulos v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir.  
4 1997) (quoting Meyers v. Penny Pack Woods Home Ownership  
5 Association, 559 F.2d 894, 905 (3d Cir. 1977)). That line of  
6 authority makes clear that the availability of alternative  
7 sanctions and importance of the potentially excluded evidence  
8 should be considered prior to excluding the evidence at  
9 trial. Here, in this important case, the undersigned is  
10 especially hesitant to exclude what the parties seem to think  
11 could be important evidence and has strained to avoid it.

12 The Court will now address plaintiff's request to  
13 strike the allegedly improperly obtained and untimely hearsay  
14 aspect of the expert report. Plaintiff claims that  
15 Dr. Blobel's expert report relies on statements from the fact  
16 declaration by third party Dr. Bruce Beutler of the  
17 University of Texas at Southwestern. Plaintiff claims that:  
18 (1) The fact declaration from Dr. Beutler received after the  
19 close of fact discovery is "severely prejudicial," and it  
20 should not be permitted to be used for "any purpose" in the  
21 case, and (2) "under the guise of giving expert testimony,  
22 Dr. Blobel improperly repeats ... uncorroborated dates and  
23 descriptions from the [declaration] in his report."

24 The request to strike will be denied subject to the  
25 subject being raised as an *in limine* motion. First, there

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1 has been no showing that the declaration was improperly  
2 obtained. Dr. Beutler was issued a subpoena on May 26, 2017;  
3 served on June 3, which was nearly a month before the close  
4 of fact discovery on June 30. Dr. Beutler filed a motion to  
5 quash in the Northern District of Texas on June 20.

6 On June 21, the Northern District of Texas ordered  
7 the parties to meet and confer and submit a joint submission  
8 summarizing their conference.

9 In a July 5 email, Immunex's counsel stated that it  
10 believed that the subpoena was served late in the discovery  
11 process and that "it does not seek the deposition of  
12 Dr. Beutler" and that Immunex would "attend a deposition if  
13 the Court orders one to be conducted."

14 On July 12, the parties advised the Court in the  
15 Northern District of Texas that they had reached an agreement  
16 on the subpoena, which was to accept a declaration from  
17 Dr. Beutler in lieu of deposition. The declaration was  
18 provided on August 18 and provided to Immunex's counsel on  
19 the same day. It should be noted that the parties took  
20 depositions through July and August after the close of  
21 discovery, with the last deposition being held on August 9,  
22 which was nine days prior to the declaration being provided.  
23 This history shows that, while late in the period, the  
24 subpoena was served in the discovery period. And the  
25 meet-and-confer process was directed by a federal judge in

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1 Texas.

2 As for whether Dr. Blobel's report contains hearsay  
3 in the form of improperly repeating uncorroborated dates and  
4 descriptions from the 2017 Beutler declaration," this is  
5 really an evidentiary issue for the trial judge at a later  
6 time. Both sides cite authority for their positions, but the  
7 authority is not dispositive of the issue. The Marvel case  
8 cited by plaintiff is a summary judgment and Daubert opinion  
9 that involved a supposed expert who "did not bring expertise  
10 to bear in any way" and basically was just aggregating  
11 hearsay comments from freelance artists in the comic book  
12 industry. See 726 F.3d 119, 136 (2d Cir. 2013). The  
13 Monsanto case is cited for the fairly basic conclusion that  
14 experts need not have obtained the basis for his [or her]  
15 opinion from personal perception," and that a report may "be  
16 based on facts or data that themselves are inadmissible."  
17 These cases reinforce the fact that expert reports may and  
18 often are based on hearsay information, and the admissibility  
19 of same is an issue of evidence to be decided by the trial  
20 judge.

21 Therefore, the Court will not strike that any  
22 aspect of the Blobel report on that basis at this time. Any  
23 challenge to the Blobel report and its reliance on the  
24 Beutler declaration should be made at the *in limine* phase of  
25 the case.

Having said that, given the circumstances of the preparation and production of the Beutler declaration, the plaintiff is permitted to serve a subpoena on Dr. Beutler, if it so chooses, and to attempt to take his deposition.

5 That is the end of the Opinion. It should also be  
6 noted that this opinion is going to be temporarily sealed  
7 pursuant to 5.3. The parties have requested that the  
8 information reflecting highly confidential patent information  
9 is subject to protection and will be filing a formal motion  
10 to seal. Until that occurs, this Opinion should be sealed.  
11 And as said before, it should be provided to the Court for  
12 proofreading and correction pursuant to Local Rule 52.1.

13 (Conclusion of proceedings)

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1 | Certification

2 I, SARA L. KERN, Transcriptionist, do hereby certify  
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11 I further certify that I am in no way related to any of  
12 the parties hereto nor am I in any way interested in the  
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